UNITED STATES DISTRICT COURT EASTERN DISTRICT OF WISCONSIN

United States of America, ex. rel.

Jennifer Denk 2000 Rambling Rose Road Waukesha, WI 53186, Plaintiff,

Filed *In Camera* pursuant to 31 U.S.C. § 3730(b)(2).

Civil Action, File No. ____

v.

PharMerica Corporation 1901 Campus Place Louisville KY, 40299,

Defendant.

FIRST AMENDED COMPLAINT

Plaintiff, United States of America *ex rel*. Jennifer Denk, through her attorneys, Cross Law Firm, S.C., complains and alleges the following:

I. Parties

- 1. Relator, Jennifer Denk, is a citizen of the United States of America and a resident of the State of Wisconsin, residing at 2000 Rambling Rose Road in the City and County of Waukesha, State of Wisconsin 53186. At all material times Denk was and is a pharmacist licensed in the States of Wisconsin, No. 15014-040, and Alaska, No. 1810 and was employed by Defendant PharMerica Corporation as a Pharmacy Operations Manager in PharMerica Corporation's Pewaukee, Wisconsin facility.
- 2. Relator brings this action on behalf of the United States of America pursuant to 31 U.S.C. § 3730(b)(1). The United States of America is a sovereign country whose Department of

Health and Human Services pays claims submitted to it by PharMerica Corporation through the Medicaid and Medicare programs for prescription medications and other pharmaceutical products.

- 3. PharMerica Corporation is a Delaware corporation with its principal place of business at 1901 Campus Place in the City of Louisville, State of Kentucky 40299. PharMerica Corporation was formed as the integration of two nationwide pharmaceutical services companies: Kindred Pharmacy Services (KPS) and PharMerica, Inc. PharMerica Corporation operates and manages long term care pharmacies and long term acute care hospital pharmacies across the country.
- 4. According to its website: "PharMerica Corporation maintains high standards of quality care and customer-defined services, combining cost-effective management with clinical excellence. Our technologically advanced dispensing and tracking systems ensure quality care and accurate provisions of medication." PharMerica also states on its website: "Our mission is to lower our customers' prescription costs while at the same time, improving the quality of patient care."

II. Jurisdiction and Venue

- 5. Jurisdiction lies in this Court pursuant to 28 U.S.C. §§1331, 1345 and 31 U.S.C. §3732(a).
- 6. Venue is proper in the Federal District Court, Eastern District of Wisconsin *inter alia*, pursuant to 28 U.S.C. §1391(a) because a substantial part of the events or omissions giving rise to the claim occurred in this judicial district.
- 7. Before filing this lawsuit, Relator met with United States Drug Enforcement
 Administration (DEA) investigators and with Department of Justice (DOJ) assistant U.S. attorneys
 to provide information and to notify them of her intent to file this action.

III. Statement of the Action

- 8. This action is brought on behalf of the United States of America to recover all damages, penalties and other remedies established by and pursuant to 31 U.S.C. §§3729-3733, and on behalf of Relator Jennifer Denk to claim entitlement to a portion of any recovery obtained by the United States as a *qui tam* plaintiff authorized by 31 U.S.C. §373 including §3730(h) for retaliatory discharge.
- 9. Relator brings this action to impose liability upon Defendant for violations of 31 U.S.C. §3729, the federal False Claims Act (FCA). Defendants' liability arises from its submission to the United States of false and fraudulent claims for monetary payment for the sale of prescription drugs and other pharmaceutical products which PharMerica represented it sold to individuals entitled to payment through the Medicare and Medicaid programs. Such claims were not eligible for payment due to PharMerica's non-compliance with Medicare, Medicaid, and other laws and regulations relating to the dispensing, control, sale, billing, and disbursement of pharmaceutical products, including Schedule II, III, IV and V controlled substances, see 21 U.S.C. §812 (Uniform Controlled Substances Act of the States). Defendant's liability also arises from kickbacks to its vendors and from its retaliatory discharge of relator.

IV. Background

PharMerica Corporation

- 10. In or about 2007 PharMerica, Inc., a subsidiary of AmerisourceBergen

 Corporation, and Kindred Healthcare, Inc. merged to form PharMerica Corporation.

 AmerisourceBergen Corporation, a pharmaceutical wholesaler and distributor remains the primary provider of prescription drugs to PharMerica.
- 11. Defendant purchases and resells prescription drugs and other pharmaceutical products to patients in hospitals, skilled nursing facilities ("SNFs"), and assisted living facilities

("ALFs") through contracts with those facilities. PharMerica operates approximately 95 closed retail pharmacies in approximately 41 states that serve approximately 320,000 licensed beds for patients of long-term care and other facilities. PharMerica's closed retail pharmacies are licensed to purchase and dispense Schedule II-V controlled substances.

- 12. According to the February 2009 10-K report that Defendant filed with the United States Securities and Exchange Commission ("SEC"), in 2008 PharMerica's revenue derived from Medicare Part D reimbursements was \$885.8 million; its revenue derived from Medicaid reimbursements was \$181.1 million; and its revenue derived from Medicare reimbursements was \$10.1 million. Upon information and belief, approximately 90% of the individuals who receive medications from PharMerica are participants in either Medicare or Medicaid.
- 13. Nationwide, PharMerica has approximately 6,600 employees. Its corporate Regulatory Affairs, Human Resource, and Legal Departments are responsible for ensuring Defendants' compliance with applicable laws and regulations.
- 14. Defendant provides pharmacy consulting and other services to its customers and employs "Consulting Pharmacists" for this purpose. According to its policies, Defendant has three management positions in each of its closed retail pharmacies: General Manager/Director of Operations, Operation/Pharmacy Manager, and Pharmacist-in-Charge; however, historically, many of these positions have gone unfilled for extended periods of time, requiring the remaining subordinate employees to maintain and increase the requisite sales, billing and shipping volumes. Defendant also employs "narc techs", "order entry techs", "fill techs", and "pack techs" to process its drug orders; and it contracts with vendors for the delivery of medications and other products to the facilities under contract with Pharmerica.
- 15. During all relevant times, Defendant's lack of staffing, lack of employee training and orientation, lack of appropriate policies and procedures, productivity requirements, and

general methods of operation enabled Pharmerica to commit caused regular and repeated violations of legal requirements governing the handling and dispensing of controlled substances and to submit false claims to the United States for payment of controlled substances which were illegally dispensed or not dispensed at all.

- 16. During all relevant times, throughout the United States Defendant knowingly hired candidates for managerial pharmacy positions with insufficient or no experience in a closed retail pharmacy setting for its Managerial Pharmacist positions.
- 17. During all relevant times, Defendant required Pharmacy Operations Managers in its facilities to sign employment contracts providing for the payment of ten thousand dollars (\$10,000) or other significant sums if they resigned their employment under any circumstances within two years of their start date. The forfeiture applies even if the employee resigns in response to illegal practices at Defendant's facilities.

Defendant's Sale & Billing of Controlled Substances

- 18. Although Defendant has adopted certain formal policies for the processing of medication orders, it has intentional failed to actually promulgate and distribute its policies and procedures relating to the dispensing of controlled substances to its employees. Specifically, Defendant does not routinely or regularly provide training or orientation on the dispensing of controlled substances to its Pharmacy Operations Managers who are charged with oversight of staff pharmacists and billing practices.
- 19. Defendant does not utilize software to track its inventory of controlled substances or to record the receipt of signed prescriptions for controlled substance orders that are required by federal law and regulations.
- 20. Defendant stresses productivity requirements to obtain and fill drug orders as priorities for its pharmacy employees.

- 21. When Defendant's pharmacies receive orders for controlled substances, employees known as Order Entry Techs electronically enter the information into the "AS 400" software application. The hard copy orders are also organized into corresponding batches of approximately 20 orders which are assigned a batch number. A staff pharmacist (RPH-1) then verifies the accuracy of the entered data, and the software automatically assigns a prescription number. The pharmacist then closes and releases the batch to PharMerica's corporate Regional Billing Office ("RBO") in Longmont, Colorado.
- 22. The AS 400 program transfers the approved batch to "fill" status and prints labels for the medications. Employees known as Fill Techs then fill the orders for prescription medications from the PharMerica inventory. The majority of the drugs are put into a Unit Dose Package, referred to as a "Bingo Card". The AS 400 prints a manifest that is matched to a batch for delivery by a private contract delivery company that makes deliveries twice daily on weekdays and once daily on weekends.
- 23. From the Pewaukee facility alone, Defendant fills approximately 56,000 drug orders monthly, an estimated 12%, or more than 200 orders per day of which are for Schedule II-V controlled substances.
- 24. Defendant supplies SNFs with separate containers known as "narc boxes".

 Schedule II controlled substances and Schedule III-V controlled substances are kept in separate narc boxes. PharMerica regularly refills the narc boxes without regard to required documentation and control over the disposition of their contents.
- 25. Before filling and shipping orders, PharMerica pharmacies send them to Regional Billing Offices ("RBOs") which verify that the patient is covered by a federally funded health care insurance program. The Pewaukee pharmacy sends orders to a Colorado RBO for billing to the United States Government for payment through its federally funded programs including Medicare

Parts A and D, CHAMPUS/TRICARE, Wisconsin Medicaid, Wisconsin Senior Care Medicaid, Illinois Medicaid, Iowa Medicaid, Indiana Medicaid, Minnesota Medicaid, Michigan Medicaid, and South Dakota Medicaid, for example.

26. During all relevant times, the Pewaukee, Wisconsin PharMerica facility provided drugs to approximately 50 long-term care facilities in Wisconsin and the Michigan Upper Peninsula.

Relator and Her Whistleblowing Activities

- 27. From on or around October 30, 2008 until her July 23, 2009 termination, Relator Jennifer Denk was employed by PharMerica as the Pharmacy Operations Manager ("POM") for the Pewaukee, Wisconsin PharMerica facility.
- 28. As the Pewaukee, Wisconsin POM for PharMerica, Relator's duties included directing and managing the pharmacy staff; communicating with SNFs and ALFs, physicians, and related personnel involved in the purchasing of prescription drugs and other pharmaceutical products through PharMerica; working with PharMerica management to ensure compliance with state and federal regulations; and maintaining inventory and recordkeeping for controlled drugs.
- 29. Beginning on or around March 16, 2009 and continuing frequently thereafter, Relator began raising questions with other members of management, including those charged with compliance with federal laws and regulations, regarding the manner in which Defendant was handling, selling, billing, and dispensing controlled substances.
- 30. On April 27, 2009 Relator informed her supervisor, Melissa Maupin ("Maupin"), General Manager of the Pewaukee facility, of her concern that PharMerica's practices and procedures related to the dispensing of Schedule II-V controlled narcotics were not compliant with federal regulations. Maupin directed Relator to continue PharMerica's normal business practice of dispensing scheduled narcotics in alleged "emergency situations" without ensuring that a written

prescription or physician's signature is on file within seven days, in violation of federal controlled substances regulations

- 31. On information and belief, Defendant's Pewaukee, Wisconsin and corporate-level management knew that these practices and procedures were not compliant with federal regulations.
- 32. On May 1, 2009, Heidi Papenthien ("Papenthien"), PharMerica's Pewaukee, Wisconsin human resources representative, directed Relator "not to worry" about a scheduled internal corporate compliance audit because PharMerica would "fix it later.", meaning the non-compliance with federal controlled substance regulations would be fixed later.
- On May 6, 2009, Relator sent an e-mail to Maupin reiterating her concern that PharMerica was violating federal regulations governing the handling of Schedule II-V controlled narcotics in each of the following respects: (a) by failing to secure signed prescriptions within the requisite seven days after dispensing narcotics on an "emergency" basis; b) by failing to indicate any basis for an "emergency dispense"; and c) by dispensing narcotics without any signed prescription in non-emergency situations.
- 34. Maupin replied to Relator's May 6, 2009 email and stated in her own e-mail that the lack of compliance was a "global" or corporate-wide problem and that "corporate" was aware of the scope of the non-compliance. Maupin further directed Relator to take no action to accomplish compliance until the Corporate Director of Regulatory Compliance, Sharon Hartman ("Hartman"), came to the facility. Maupin stated that the Pewaukee facility could not make changes to procedures without Corporate directives. Maupin reiterated that Relator was not to make compliance changes, as they would "upset the customers". "Customers" are SNF's and ALF's.

- 35. On May 4, 2009 Relator called the United States Drug Enforcement Administration ("DEA") and spoke to Diversion Investigator Thomas B. Hill, informing him about PharMerica's non-compliance issues.
- department is and has been aware of non-compliance and false billing practices in its facilities, but has taken no systematic efforts to accomplish compliance which would impede profits. Hartman and Dan Staffieri ("Staffieri"), a Regulatory Consultant employed by PharMerica, visited the Pewaukee, Wisconsin facility on May 11 and 12, 2009 to conduct a "corporate audit". On information and belief, they did not actually "audit" anything at the facility. Relator showed Hartman and Staffieri a large number of unsigned orders for controlled substances that had been dispensed and billed to the United States substantially more than seven (7) days before. Staffieri told Relator that she should "get them cleaned up" because if the government audited them they could get \$10,000 fine for each one. Staffieri also asked Relator to add a space to indicate "Emergency Dispense" on the AS 400-generated template to justify dispensing controlled substances without a signed prescription and to do so without regard to whether PharMerica had any information to suggest that there was in fact any valid emergency to dispense the controlled substances without a prescription.
- 37. During the "corporate audit," PharMerica's Director of Regulatory Compliance and its Compliance Consultant did not provide any policies or suggest any procedures to accomplish compliance; they did not direct Relator or others to cease billing the United States for claims for dispensed controlled substances which did not comply with legal and other requirements; they did not direct Relator or others to credit the United States for falsely billed claims; and they did not direct Relator or others to notify the DEA of compliance violations.

- 38. In mid-May 2009, Relator also told PharMerica's corporate compliance agents that the SNFs under contract with PharMerica were using the PharMerica provided narcotic boxes for Schedule II substances and for Schedule III-V substances like "candy jars" and that PharMerica's lack of oversight violated legal and billing requirements.
- 39. PharMerica's practices were and are that: when the narcotic boxes are returned for refill, pharmacists are to cover the fill with a 60-day prescription already on file for the patient to whom the controlled substance was dispensed, if possible; narcotic box usage is not reconciled; and narcotic boxes are refilled without the existence of valid prescriptions for the refills.

 Defendant's corporate auditor demonstrated a lack of concern about the "candy jar" usage and systematic lack of oversight and did not direct or suggest any change in practices other than to complete a DEA form if narcotics were missing.
- 40. On information and belief, at least commencing in 2008, Defendant shredded documents relating to the usage and billing for "narc boxes," in order to destroy evidence of non-compliance with federal statutes and regulations and the related false billings to the government.
- 41. On May 13, 2009, acting on information provided by Relator, the DEA inspected the premises of the Pewaukee, Wisconsin PharMerica facility. During the inspection, DEA agents noticed a stack of documents on Relator's desk and investigated them. The stack contained records of unsigned prescriptions for drugs dispensed from the previous year and usage sheets that showed medications missing from the narcotic boxes. In front of Maupin, the DEA requested that Relator send all of the documents on her desk to their offices. After the DEA left, Maupin instructed Relator not to send the documents to the DEA at that time, but to "fix" the documents by "matching" them up with old prescriptions or by obtaining physician signatures. Maupin directed Relator to only send the documents to the DEA which she could "fix" and Maupin noted that the DEA had not counted the documents and they would not know if some were missing. Responding

to these directives, Relator asked Maupin what she should tell the DEA if they asked her about compliance; Maupin replied by repeating her directives.

- 42. On June 4, 2009 Relator contacted Richard Hollar ("Hollar"), PharMerica's Corporate human resources representative, and informed him that Maupin had directed her to commit a felony in violation of 18 U.S.C. § 1001 by intentionally lying to the DEA by not reproducing the documents they requested, by tampering with documents before sending them to the DEA, and by indicating that the documents were being submitted as the DEA requested although they were not. On June 8, after receiving no response, Relator sent Hollar another e-mail asking to be released from her employment contract based on PharMerica's failure to comply with the regulations governing the dispensing of Schedule II controlled narcotics and failure to assist Relator in her effort to correct company practices. Relator specifically stated, "I have dedicated much time and effort into cleaning up a mess that was here long before my employment began. I have been met with resistance by other members of the lead team when trying to be compliant with state and federal laws." In response, Hollar informed Relator that if she resigned during the first two years of employment, she would have to repay the company a \$10,000 "signing bonus." On June 10, 2009 Hollar told Relator that he had looked into the matter and that Maupin was not asking Relator to commit a felony, but that Maupin was only "protecting the company."
- 43. In mid-June 2009, in response to the DEA visit and Relator's complaints, Maupin intentionally altered computer records of narcotic drug usage, billing, and patient usage history for controlled substances dispensed and billed to the United States for certain drug orders for which there was no physician signature.
- 44. 21 C.F.R. §1301.71 requires that "[The pharmacy] shall provide effective controls and procedures to guard against theft and diversion of controlled substances." Specifically, controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked,

substantially constructed cabinet. 21 C.F.R. §1301.75. Throughout her employment with PharMerica, Relator observed that PharMerica's Pewaukee, Wisconsin facility did not properly secure controlled narcotic substances in its narcotics storage room. Instead, PharMerica continually violated these regulations by propping open the door to the control substance storage room and leaving the cabinets unlocked during business hours where all employees have unsupervised access to the scheduled controlled substances. PharMerica employees were not provided with any corporate policies which required securing controlled substances. PharMerica billed the government for drug orders filled in the uncontrolled "narc room".

45. Every month of her employment, Relator conducted an inventory of controlled substances, either personally or by delegating the duty. In a report created on May 1, 2009 for the month of April and provided to corporate management, Relator found missing pills for the following Schedule II narcotic medications: (a) Dextroamphetamine 10mg - 25 pills; (b) Dilaudid 1mg/ml Oral Solution - 92 pills; (c) Endocet 10/325 -193 pills; (d) Methylin 5 mg -126 pills; (e) Methylin 10 mg -816.5 pill; (f) Oxycodone 5mg -1,935 pills; (g) Oxycontin 10mg -151 pills; in addition to many other medications with missing pills or liquid amounts. PharMerica took no measures to implement policies or procedures to control or report or otherwise follow-up on this or any other of Relator's reports of missing medications from the PharMerica inventory.

Summary of False Claims Act Violations

46. As set forth in the factual allegations above, on numerous occasions beginning on or before November 7, 2008, PharMerica knowingly, intentionally and willfully submitted false claims, records and statements to officials of the United States for the purpose of obtaining payment for medications which were unlawfully dispensed and in order to continue billing the government despite its conduction violation of the DEA regulations. Specifically, (1) PharMerica presented claims for payment for controlled narcotic substances based on orders that were not

valid because it (a) obtained no information to support an emergency dispense or did not note any basis for emergency dispense and dispensed controlled substances on an emergency basis without a prescription signed by a physician; (b) dispensed drugs in nonemergency situations without a prescription signed by a physician; (c) dispensed drugs in an actual emergency situation without obtaining or even attempting to obtain a prescription signed by a physician within the seven day timeframe or (d) dispensed controlled drugs in the complete absence of any prescription; (2) PharMerica did not credit the United States when drugs were returned unused and, in some instances, PharMerica then re-billed the United Stated for medications which were returned unused and previously billed to the government; (3) PharMerica billed the United States for medications allegedly administered to one patient when the medications were actually administered to other patients, including those not eligible for government payments; and (4) PharMerica billed the United States for one type of medication while providing the patient with a different type of medication, and (5) PharMerica falsified records and made false representations to the DEA in order to avoid being shut down so that PharMerica could continue to bill the government.

V. Count I. Violation of the Federal False Claims Act Claim, 31 U.S.C. § 3729 et seq.,: PharMerica's Intentional Presentation of False Claims for Payment to the United States for Schedule II Narcotics Improperly Dispensed as a §290.10 Emergency

- 47. Relator reasserts and incorporates by reference all paragraphs set forth above as if restated herein.
- 48. On information and belief, for at least two years prior to Relator commencing employment with PharMerica, each of Defendant's facilities regularly dispensed and billed the United Stated for Schedule II-V controlled substances in response to phone orders without a

signed prescription, faxed discharge orders, or physician orders despite the absence of any actual, claimed or documented emergency.

- 49. Except as set forth below, PharMerica made no follow-up to such non-prescription orders in order to obtain prescriptions or physician signatures.
- 50. During all relevant times, PharMerica regularly filled and billed to the government such orders, which are treated as "Emergency Dispense" ("ED"), with a three-day supply of the controlled substances and refilled them three to four times without regard to whether a signed prescription had been received. On information and belief, no corporate policy or procedures prohibited PharMerica facilities from engaging in these practices.
- Schedule II controlled narcotic substance without a written prescription signed by a physician. The only exception to this regulatory prohibition is in an "emergency situation." In a qualifying emergency, a pharmacist may dispense a Schedule II controlled narcotic substance upon receiving oral authorization from the prescribing physician, provided that: (1) the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period; (2) the prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in 21 C.F.R. §1306.05, except for the signature of the prescribing physician; (3) if the prescribing physician is not known to the pharmacist, he or she must make a reasonable effort to determine that the oral authorization came from a registered physician; and (4) within seven (7) days after authorizing an emergency oral prescription, the prescribing physician shall provide a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. 21 C.F.R. §1306.11(d).

- 52. 21 C.F.R. §290.10 defines an emergency situation. §290.10(b) specifically states that an emergency situation does not exist "where an appropriate alternative is available, including administration of a drug which is not a controlled substance under Schedule II of the Act".
- 53. During all relevant times, the narcotic boxes that PharMerica provided SNFs had Schedule II-V substances. While schedule III-V substances could lawfully be used in emergency situations, PharMerica was responsible for ensuring that Schedule II narcotics were not taken from the narcotic boxes unless there was no appropriate alternative treatment available. By not effectively supervising access to and use of narcotic boxes PharMerica violated federal regulations and permitted the overuse of costly Schedule II medications when less expensive and more appropriate Schedule III-V medications were available. The following are examples of times that Medicare was billed for the more costly Schedule II narcotic when less expensive and more appropriate emergency medications were available:
 - a. Medicare was billed \$27.37 for Fentanyl 12 Mcg/Hr patch that was dispensed to patient D.M. on June 20, 2009 at the South Shore facility when other appropriate alternative treatment was available.
 - b. Medicare was billed \$31.93 for Oxycontin 20mg that was dispensed to patient N.W. on May 31, 2009 at the Golden Living Sheboygan facility when other appropriate alternative treatment was available.
 - c. Medicare was billed \$50.42 for Fentanyl 50mcg/hr patch that was dispensed to patient P.H. on June 4, 2009 at the Golden Living Silver Spring facility when other appropriate alternative treatment was available.
 - d. Medicare was billed \$51.29 for Fentanyl 100 mcg/hr patch that was dispensed to patient R.G. on June 13, 2009 at the Golden Living South

- Shore facility when other appropriate alternative treatment was available.
- e. Medicare was billed \$28.71 for Oxycontin 10mg that was dispensed to patient J.N. on June 18-21 at the Door County Memorial Hospital SNF when other appropriate alternative treatment was available.
- 54. Relator has personal knowledge that PharMerica's Pewaukee, Wisconsin facility violated 21 C.F.R. §1306.11(a) by regularly dispensing Schedule II narcotics without obtaining written prescriptions more than 90% of the time. Relator has personal knowledge that PharMerica's Pewaukee, Wisconsin facility did not document or attempt to ascertain whether an emergency situation existed before dispensing Schedule II narcotics without a written prescription. By failing to verify that an emergency situation did exist, PharMerica violated 21 C.F.R. §1306.11(a) and committed fraud by seeking reimbursement for the unlawfully dispensed prescriptions
- 55. Pursuant to federal regulations 21 C.F.R. §1306.11(d)(4), pharmacists are required to notify the nearest office of the United States Food and Drug Administration ("FDA") if the prescribing physician fails to deliver a written prescription within the seven-day timeframe. Failure of the pharmacist to do so voids the authority of the pharmacist to dispense the Schedule II controlled narcotic substances without a written prescription of a prescribing physician and denies PharMerica the opportunity to submit an invoice for such controlled substances to the United States for payment because the substances were illegally dispensed. 21 C.F.R. §1306.11(d)(4).
- 56. Relator has personal knowledge that PharMerica's Pewaukee, Wisconsin facility violated 21 C.F.R. § 1306.11.(d)(4) by regularly dispensing emergency prescriptions without obtaining an oral prescription from a prescribing physician. Instead of obtaining an oral

prescription, PharMerica used old prescriptions and order forms to generate the necessary information to process, bill for, and dispense the emergency prescription. As an example:

- a. Medicare was billed by PharMerica for the medication for patient J.E. without obtaining a written or oral prescription from the physician. On June 14, 2009 PharMerica dispensed Fentanyl 50mcg (a Schedule II controlled narcotic substance) to an SNF for patient J.E. based on old order forms, and without a valid prescription.
- b. Medicare was billed by PharMerica for the medication for patient J.E. without obtaining a written or oral prescription from the physician. On May 16, 2009 PharMerica dispensed Oxycontin 40mg (a Schedule II controlled narcotic substance) to an SNF for patient J.E. based on old order forms, and without a valid prescription.
- 57. The United States of America has been damaged by all of the aforementioned misrepresentations and failures to comply with requisite agreements and regulations in an amount which is yet to be determined. With respect to the said misrepresentations and failures to comply, PharMerica knowingly made false claims to officials of the United States for the purpose of obtaining compensation.
- 58. On information and belief, PharMerica's other facilities also follow the same practices of intentional non-compliance and false billing. On information and belief, PharMerica's corporate offices are aware of the non-compliant practices, condone and encourage such practices, and have not taken action to accomplish compliance, which would substantially reduce corporate profits.

VI. Count II. Violation of the Federal False Claims Act 31 U.S.C. § 3729 et seq.:

PharMerica's Intentional Presentment of Claims for Payment to the United States for

Schedule II Narcotics Which Were Dispensed As A § 290.10 Emergency Without A Signed Prescription

- 59. Relator reasserts and incorporates by reference all paragraphs set forth above as if restated herein.
- 60. PharMerica's Pewaukee, Wisconsin facility regularly did not obtain or attempt to obtain physician signatures within the required seven-day timeframe for controlled substances dispensed in emergency situations and PharMerica knowingly submitted claims for payment of such dispensed controlled drugs, including the following specific examples:
 - a. Patient H.N. residing at the Three Oaks facility was dispensed Oxycontin 10mg on June 5, 2009. Oxycontin is a Schedule II controlled narcotic as defined in 21 C.F.R. §1308.12(b)(1)(xiii). PharMerica billed the United States through its Medicare program for the said controlled drugs on or around the same date. As of June 30, 2009 no physician's signature was obtained for the prescription, in violation of the seven day requirement of 21 C.F.R. §1306.11(d).
 - b. Patient N.B. residing at the Mt. Carmel Milwaukee facility was dispensed Endocet 5-325 on June 3, 2009. Endocet 5-325 is a Schedule II controlled narcotic as defined in 21 C.F.R. §1308.12(b)(1)(xiii). PharMerica billed the United States through its Medicare program for the said controlled drugs on or around the same date. As of June 17, 2009 no physician's signature was obtained for the prescription in violation of the seven day requirement of 21 C.F.R. §1306.11(d).
 - c. Patient M.K. residing at the KPS Wausau facility was dispensed Fentanyl 12mcg on June 5, 2009. Fentanyl is a Schedule II controlled narcotic as

- defined in 21 C.F.R. §1308.12(c)(9). PharMerica billed the United States through its Medicare program for the said controlled drugs on or around the same date. As of June 17, 2009 no physician's signature was obtained for the prescription in violation of the seven day requirement of 21 C.F.R. §1306.11(d).
- d. Patient JC.M residing at the KPS- Woodstock facility was dispensed Endocet 5-325 on May 27, 2009. Endocet 5-325 is a Schedule II controlled narcotic as defined in 21 C.F.R. §1308.12(b)(1)(xiii). PharMerica billed the United States through its Medicare program for the said controlled drugs on or around the same date. As of June 17, 2009 no physician's signature was obtained for the prescription in violation of the seven day requirement of 21 C.F.R. §1306.11(d).
- e. Patient A.T. residing at the Colonial Manor Milwaukee facility was dispensed Oxycontin 20mg on March 5, 2009. Oxycontin is a Schedule II controlled narcotic as defined in 21 C.F.R. §1308.12(b)(1)(xiii). PharMerica billed the United States through its Medicare program for the said controlled drugs on or around the same date. As of June 2, 2009 no physician's signature was obtained for the prescription in violation of the seven day requirement of 21 C.F.R. §1306.11(d).
- f. Patient J.B. residing at the Colonial Manor Milwaukee facility was dispensed Fentanyl 25mcg on March 5, 2009. Fentanyl is a Schedule II controlled narcotic as defined in 21 C.F.R. §1308.12(c)(9). PharMerica billed the United States through its Medicare program for the said controlled drugs on or around the same date. As of June 2, 2009 no

- physician's signature was obtained for the prescription in violation of the seven day requirement of 21 C.F.R. §1306.11(d).
- g. Patient W.M. residing at the Colonial Manor Milwaukee facility was dispensed Oxycodone HCL 5mg on March 6, 2009. Oxycodone is a Schedule II controlled narcotic as defined in 21 C.F.R. §1308.12(b)(1)(xiii). PharMerica billed the United States through its Medicare program for the said controlled drugs on or around the same date. As of June 2, 2009 no physician's signature was obtained for the prescription in violation of the seven day requirement of 21 C.F.R. §1306.11(d).
- 61. PharMerica was aware of the requirement to obtain the prescribing physician's signature within seven days after the emergency prescription, yet Defendant knowingly submitted false claims for payment without having obtained or attempted to obtain the requisite signature within the allowable timeframe and without notifying the proper authorities. Because it failed to comply with the requirements of 21 C.F.R. §1306.11(d)(4), PharMerica did not have the authority to dispense controlled narcotic medications or to bill the United States Government for such dispensed controlled substances.
- 62. On information and belief, for at least two years prior to Relator's hire with PharMerica and during her employment before Relator complained about the above non-compliance, Defendant took no measures and provided no staff to obtain signed prescriptions for dispensed Schedule II controlled substances and submitted claims for payment by the government without regard to such pre-conditions for payment.
- 63. On information and belief, PharMerica's other facilities also followed the same practices of intentional non-compliance and false billing. On information and belief, PharMerica's

corporate offices are aware of the non-compliant practices and took no action to accomplish compliance which would substantially reduce corporate profits.

- On May 18, 2009, Defendant's corporate office sent a memo to the facilities it has under contract, stating that effective immediately, in order to qualify for the emergency exception so that a signed prescription is not required before dispensing controlled substances, the patient must be either a new admission or the drug order must be must be a new order for the controlled substance. Prior to that time, there was no policy requiring any basis for the emergency exception. Further, PharMerica's new policy does not comply with federal regulations and has perpetuated the regular practice of submitting false claims for payment to the United States.
- 65. On information and belief, PharMerica has scores of boxes of orders for controlled substances which were dispensed and billed to the United States without a signed prescription from a physician secured within the seven-day time frame (if ever). With regard to most if not all of these orders, PharMerican made no attempt to obtain the required signed prescription.
- 66. On June 16, 2009, Relator learned of and observed in the so-called "Harry Potter" room of PharMerica's Pewaukee facility, boxes of unsigned prescriptions and orders that had been billed to the United States and that management had intentionally concealed. These boxes were approximately the standard sized banker's boxes, which are 10"H x 12"W x 24"D. A similar sized printer paper box stores 3,000 neatly packed sheets of individual paper. Upon information and belief, each banker's box contains approximately 2,000-3,000 unsigned and illegally-billed prescriptions or orders in violation of 21 C.F.R. §§ 1306.11(a) and (d)(4). Relator pulled random samples of the unsigned orders for prescription medications and checked their billing history in the PharMerica AS400 system. Relator found, for example:
 - a. PharMerica billed Medicare and Wisconsin Medicaid for Colonial Manor patient, R.L., who was given two separate doses of Fentanyl (one 25 mcg,

the other 50 mcg) without a signed prescription within seven days, a violation of 21 C.F.R. § 1306.11(d)(4). The medication was dispensed on July 3, 2007 but the signature from the doctor was still missing as of June 16, 2009 when Relator discovered the prescription document.

- b. PharMerica billed Michigan Medicaid for MaryHill Manor patient, I.W., who was given Fentanyl 25 mcg on April 3, 2007. The prescription was still unsigned when Relator discovered it on June 16, 2009.
- Relator has personal knowledge that PharMerica's practice of billing the United 67. States Government for dispensed controlled narcotic medications without a valid prescription is followed at other PharMerica locations. In an e-mail dated November 3, 2008 from PharMerica Director of Corporate Compliance/Regulatory Affairs, Sharon Hartman to Jay Palin, Vice President of Operations, and Robert Nolan, Vice President & Chief Compliance Officer, and subsequently forwarded to Relator, Hartman states that there were outstanding billed Schedule II controlled narcotic substance prescriptions unsigned after seven (7) days at the following PharMerica locations: 989 in Warren, MI; 236 in Fridley, MN; 81 in Worthington, OH; 104 in Nashville, TN; and 171 in Pewaukee, WI. The e-mail was forwarded to all PharMerica General Managers, including Maupin who forwarded it to Relator to have her conduct the research into the outstanding prescriptions for the Pewaukee, Wisconsin PharMerica. The total amount of current billed and unsigned prescriptions from those five locations at that time in that region alone was in excess of sixteen hundred (1600) not including the older boxed billed and unsigned prescriptions, which dated back to at least the beginning of 2007. PharMerica intentionally billed the United States Government for the invalid prescriptions which, due to violations of 21 C.F.R. §1306.11(d)(4) never were eligible for reimbursement.

- 68. Relator has personally viewed prescriptions that remain unsigned, but were filled and billed as far back as April 3, 2007. Defendant was aware no later than November 3, 2008 that it was in violation of regulations regarding billed Schedule II controlled narcotic substance prescriptions unsigned after seven days. At least as early as November 3, 2008, Defendant requested from several of its locations their status on the number of billed Schedule II controlled narcotic prescriptions unsigned after seven days. Upon information and belief, Defendant continued to monitor the number of billed schedule II controlled narcotic prescriptions unsigned after seven days but took no action to prevent billing for the non-compliant prescriptions.
- 69. After Relator complained about the illegal practices, in an e-mail dated April 1, 2009 sent on behalf of Palin from Karanne Isler, his administrative assistant, to all PharMerica general managers, Palin stated that recovery of the unsigned outstanding prescriptions was a priority that needed attention. Maupin forwarded this e-mail to Relator so that she would prepare the weekly report on the outstanding prescriptions. Some of the unsigned prescriptions had been outstanding from 2008. At the request of Maupin, Relator began contacting physicians to get them to sign the prescriptions, even though signatures secured months or even years later are invalid. In an e-mail dated April 2, 2009, Maupin instructed Relator to secure the signatures anyway: "I know it's not exactly a signed script, but it's better than nothing and might be somewhat of a defense if we were to be unfortunate enough to get audited."
- 70. In an e-mail dated April 20, 2009, Relator informed Maupin that employees in the Data Entry division of PharMerica Pewaukee, Wisconsin were not assisting in the recovery of outstanding prescriptions, as was ordered in the April 1, 2009 e-mail. On information and belief, Maupin took no action in response to this e-mail.
- 71. During all relevant times and on a regular basis PharMerica's SNF customers dispensed Schedule II controlled narcotic substances to patients prior to PharMerica's receipt of a

valid prescription. As representative examples, the patients listed in paragraph 60 above all received their medications from a narcotic box prior to receipt by PharMerica of a valid prescription. PharMerica routinely bills the United States Government for the Schedule II controlled narcotic substances dispensed without a prescription.

- 72. The United States of America has been damaged by all of the said misrepresentations and failures to comply with requisite agreements and regulations in an as of yet undetermined amount. With respect to the aforementioned misrepresentations and failures to comply, PharMerica knowingly made false claims to officials of the United States for the purpose of obtaining compensation.
- 73. On information and belief, PharMerica's other facilities have followed the same or similar practices of intentional non-compliance and false billing. On information and belief, PharMerica's corporate-level management is aware of the non-compliant practices, condone and encourage such practices, and have failed to take action to accomplish compliance which would substantially reduce corporate profits.

VII. Count III Federal False Claims Act Claim pursuant to 31 U.S.C. § 3729 et seq.: PharMerica's Intentional Submission of Claims for Payment to the United States for Schedule III, IV and V Narcotics Dispensed in Violation of the Law.

- 74. Relator reasserts and incorporates by reference all paragraphs set forth above as if restated herein.
- 75. Pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301 *et seq.*, scheduled controlled narcotic substances may only be dispensed upon a written prescription of a practitioner licensed by law to administer such drug, or upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the

original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. A physician's order does not qualify as a valid prescription pursuant to 21 C.F.R. § 1306.05(a), as it does not contain the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner.

- 76. With regard to Schedule III, IV, or V controlled narcotics, a pharmacist may dispense these medications pursuant to either a written prescription signed by a physician or a facsimile of a written, signed prescription transmitted by the physician or the physician's agent to the pharmacy. Additionally, a pharmacist may dispense Schedule III, IV, or V controlled narcotic substances pursuant to an oral prescription made by a physician and promptly reduced to writing by the pharmacist only if it contains all information required in 21 C.F.R. §1306.05 other than the physician's signature.
- 77. Relator has personal knowledge that PharMerica routinely dispensed Schedule III, IV and V controlled narcotic substances and billed the United States government for those medications based solely on physician's orders which did not comply with the requirements of 21 C.F.R. §1306.05(a) and without obtaining a valid prescription. For example only PharMerica billed the government through Medicare for the Schedule III controlled narcotic substance Hydrocodone 5-325, 5-500, 10-325 for the following three patients based solely on a physician's order: (a) patient I.K. at the Mt. Carmel Milwaukee facility on June 16, 2009;(b) patient D.K. at the Beaver Dam facility on June 9, 2009, and (c) patient L.J at the Wisconsin Dells facility on June 12, 2009.
- 78. The United States has been damaged by all of the said misrepresentations and failures to comply with requisite agreements and regulations in an as of yet undetermined amount.

With respect to the said misrepresentations and failures to comply, PharMerica knowingly made false claims to officials of the United States for the purpose of obtaining compensation.

79. On information and belief, PharMerica's procedures are known and condoned at the corporate level and its other facilities follow the same or similar practices of intentional non-compliance and false billing. On information and belief, PharMerica's corporate-level management is aware of the non-compliant practices and has intentionally caused such practices to continue because compliance would substantially reduce corporate profits.

VIII. Count IV Federal False Claims Act Claim pursuant to 31 U.S.C. § 3729 et seq. : PharMerica's Failure to Credit Payments Made by the U.S. Government and Double Billing for Returned Medications

- 80. Relator reasserts and incorporates by reference all paragraphs set forth above as if restated herein.
- 81. Relator has personal knowledge of Defendant's regular practices of: 1) failing to credit the United States Government for medications that were billed but subsequently returned and 2) billing the United States Government more than once for these same medications.
- 82. On information and belief, PharMerica's other facilities have also engaged in the same or similar practices of intentional failure to credit and double billing. On information and belief, PharMerica's corporate-level management is aware of these practices, condoned and encouraged them, and has not taken action to accomplish compliance which would substantially reduce corporate profits.
- 83. Relator has personal knowledge that PharMerica regularly relabeled drugs that were previously billed and submitted to the United States for payment.
- 84. As an, example only, when medication was returned to PharMerica because the patient was discharged or deceased, or the medication was discontinued, pursuant to management

directive PharMerica technicians would receive the returned medications, peel off the label, and place the label on a "Prescriptions for Credit" sheet. Subsequently, the technicians would place the unlabeled packages back on the shelf inventory; however, PharMerica's regular practice is to not credit the United States for the returned medications.

- 85. Relator personally accessed the billing data in PharMerica's AS400 system and observed that, as of July 1, 2009, PharMerica had failed to credit the United States Government for any of the following prescriptions which had been returned to PharMerica's inventory and which were to be re-dispensed and re-billed later: :
 - a. Patient C.J. at the Woodstock facility was sent Schedule II narcotic controlled substance Oxycodone on June 22, 2009 that was subsequently returned but not credited;
 - b. Patient C.B. at the Dorchester facility was sent Schedule II narcotic controlled substance Fentanyl on June 12, 2009 that was subsequently returned but not credited;
 - c. Patient I.B. at the Three Oaks facility was sent Schedule II narcotic controlled substance Morphine Sulfate on June 15, 2009 that was subsequently returned but not credited;
 - d. Patient R.G. at the Silver Spring facility was sent Schedule II narcotic controlled substance Endocet on June 13, 2009 that was subsequently returned but not credited.
- 86. Medications billed to the United States government and sent to Defendant's customers are regularly packaged in blister pack cards, which are known in the industry as "Bingo Cards". These cards are used so that one dosage may be handled without the other dosages becoming contaminated. Each card contains a fixed supply of medications, usually a weekly or

monthly amount. PharMerica staff either created cards from bulk medications, or the cards would arrive at PharMerica already packaged by the pharmaceutical manufacturer. Entire cards would then be billed, shipped to PharMerica's customers and dispensed to individual patients.

- 87. Defendant's SNF customers regularly returned unused or partially unused "Bingo Cards" to PharMerica. This would occur, for example, if a patient died or was no longer under the customer's care. When "Bingo Cards" containing medications which had been billed to the United States were returned to PharMerica, PharMerica's practice was to not credit the United States for the unused medication. Instead a) the card would be destroyed with no credit given; b) the unused medication from a partially used card would then be taken to fill a different order for which the United States government would again be billed; or c) whole unused cards were relabeled and again billed to the United States government for a new patient. For example, medications dispensed in "Bingo Cards" to patients C.J. and R.G. above were subsequently returned and upon information and belief, redispensed and rebilled.
- 88. Relator has personal knowledge that PharMerica regularly billed the government for prescriptions that were sent to deceased patients. A November 9, 2008 e-mail sent to Relator from Lisa Oare-Shanks, PharMerica's Vice President of National Accounts, noted that Defendant continued to send medications to its SNF customers which were designated for patients who were already deceased. Upon information and belief, these medications were intentionally sent to dead patients, billed to the United States Government and intentionally not credited back.
- 89. The United States of America has been damaged by all of the aforementioned misrepresentations and failures to comply with requisite agreements and regulations in an as of yet undetermined amount. With respect to the said misrepresentations and failures to comply, PharMerica knowingly made false claims to officials of the United States for the purpose of obtaining compensation.

90. On information and belief, PharMerica's other facilities have engaged in the same practices of intentional non-compliance and false billing. On information and belief, PharMerica's corporate-level management is aware of the non-compliant practices and has taken no action to accomplish compliance which would substantially reduce corporate profits.

IX. Count V Federal False Claims Act Claim pursuant to 31 U.S.C. § 3729 et seq.: Submission of Other False Claims for Payment – Drugs Dispensed to Individuals Without a Prescription; Drugs Dispensed in Place of those Prescribed

- 91. Relator reasserts and incorporates by reference all paragraphs set forth above as if restated herein.
- 92. Relator has personal knowledge of Defendant's regular practice of billing the
 United States Government for medications dispensed to individuals who do not have a
 prescription for the medications that were dispensed. As the Pharmacy Operations Manager,
 Relator had access to and created Pharmacy Dispensing Occurrences (PDOs) into the PharMerica
 intranet.
- 93. As a representative example, the following PDOs detail how PharMerica billed the United States for medications the respective patients did not receive:
 - a. On March 2, 2009, PharMerica billed the United States for Seroquel
 50mg on behalf of a Sheridan facility patient K.D., who had no such prescription;
 - b. On February 1, 2008, PharMerica billed the United States for Coumadin on behalf of a Mt. Carmel Burlington facility patient S. D., who had no such prescription;
 - c. On December 8, 2008, PharMerica billed the United States for
 Alprazolam .25 mg on behalf of a Mt. Carmel Milwaukee patient J.D.

- However, the medication was dispensed to fill the prescription of another patient, D.N., who was a Medicare patient covered by a different Medicare plan;
- d. On April 14, 2009, PharMerica billed the United States for Methylin 10 mg on behalf of a Mt. Carmel Milwaukee patient V.K. yet the medicine was delivered to N.H., a non-Medicare patient.
- 94. Relator has personal knowledge that PharMerica submitted claims for payment for one type of medication and then provided a different type of medication to the customer. By reviewing and submitting PDOs, Relator had access and first-hand knowledge of patients who had prescriptions for one medication but were given another.
- 95. As a representative example, the following individuals were provided a different type of medication than what was billed:
 - a. On February 10, 2009, PharMerica billed the United States on behalf of Eastview facility patient B.D. for Actos 30mg; however, B.D. was provided Ciprofloxacin 500mg;
 - b. On March 3, 2009, PharMerica billed the United States on behalf of Mt.
 Carmel Milwaukee patient D.N. for Flagyl 500mg; however, D.N. was provided with Metformin 500mg;
 - c. On February 10, 2009, PharMerica billed the United States on behalf of Northridge patient H.S. for Avapro 150mg; however, H.S. was provided with Calcitriol .25mg.
- 96. The United States of America has been damaged by all of the said misrepresentations and failures to comply with requisite agreements and regulations in an as of yet undetermined amount. With respect to the said misrepresentations and failures to comply,

PharMerica knowingly made false claims to officials of the United States for the purpose of obtaining compensation.

97. On information and belief, PharMerica's other facilities also engaged in the same practices of intentional non-compliance and false billing. On information and belief, PharMerica's corporate-level management was aware of the non-compliant practices and took no action to accomplish compliance which would substantially reduce corporate profits.

X. Count VI. Federal False Claims Act Claim pursuant to 31 U.S.C. § 3729 et seq.: Violations of the Anti-Kickback Statute For Steering Physicians and Individuals to Purchase Drugs Whose Manufacturers Give Rebates to PharMerica

- 98. Relator reasserts and incorporates by reference all paragraphs set forth above as if restated herein.
- 99. The Anti-Kickback Statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally-funded health care program.42 U.S.C. § 1320a-7b(b). The statute prohibits outright bribes, rebate schemes, and offering of inducements or rewards for referrals, recommendations or arrangements, and the statute places liability on both sides of an impermissible kickback relationship.
- 100. 42 C.F.R. §1001.952 creates "safe harbors" that make acceptable certain arrangements which would otherwise violate the Anti-Kickback Statute, Section 42 C.F.R. §1001.952(h) specifically provides a safe harbor for discounts or rebates. However, any party who is covered by a safe harbor must strictly adhere to all components of the safe harbor to enjoy the exemption from a violation of the Anti-Kickback Statute.
- 101. PharMerica has arranged for access/performance rebates from drug manufacturers.

 These rebates are provided by drug manufacturers to induce PharMerica to prefer the

manufacturer's product(s) and to increase the volume of that manufacturer's product(s) that are dispensed by PharMerica through its formulary. CMS has opposed this type of rebate because such rebate could cause the pharmacy to induce demand for higher-tiered or non-formulary drugs and thus increase the cost to the government. Effective in 2007, CMS required disclosure of these access/performance rebates to all Part D plan sponsors.

- 102. On information and belief, PharMerica has violated 42 U.S.C. § 1320a-7b(b) by engaging in an illegal kickback scheme with multiple drug manufacturers. PharMerica receives illegal kickbacks from these drug manufacturers by receiving rebates in exchange for fraudulently steering physicians to refer patients to purchase their products which are then billed to the United States Government.
- Management/Logistics, and Rob Godwin, PharMerica's Vice President of Clinical Program
 Development, sent an email declaring that PharMerica would be putting a "block" on Exelon
 purchases. Exelon is a drug manufactured by Novartis. The reason for the block was so
 PharMerica could steer individuals to purchase a similar drug manufactured by Pfizer called
 Aricept. On April 23, 2009, Maupin sent an e-mail to the Pewaukee, Wisconsin PharMerica staff
 to explain the importance of the block. She stated, "Exelon is a target product that is having a
 block put on purchasing so that the effort is made to switch the order to the preferred product,
 Aricept. [PharMerica] get[s] significant rebate[s] on Aricept, nothing on Exelon, as well as Exelon
 being a lower profit margin product as well." PharMerica also blocked another Novartis product,
 Enablex, from purchases in favor of a Pfizer product Detrol LA, on May 22, 2009.
- 104. Following the medication blocks referenced above, PharMerica implemented a procedure so that the only way that an individual can receive the blocked product from PharMerica is if a PharMerica purchaser calls the supplier and speaks with customer service to

eliminate the block for one particular instance. Pursuant to these directives, the only reason a PharMerica purchaser should make this call is if the physician insists on providing the blocked medication to the patient, or if the patient's plan will not pay for the preferred product. In all other instances, physicians were steered to the product for which PharMerica received a rebate.

- doctors and SNFs informing them of the block on Exelon in an effort to steer doctors and patients away from Exelon and towards Aricept due to the profit margin PharMerica did not inform the doctors or SNFs that they were receiving rebates on Aricept, rather they concealed that information under the guise of Aricept being a superior product to Exelon. It is immaterial if Exelon is in fact a superior product, as it is clear from Maupin and Smitherman's e-mails that the primary motivation for PharMerica to steer doctors and patients towards Aricept was profit.
- 106. On information and belief, the "rebate" program details were not disclosed to any of the following parties: Part D sponsors, Medicare, Medicaid, the patients receiving the drugs or the doctors prescribing the drugs. By not disclosing the rebate details, PharMerica cannot claim the safe harbor under 42 C.F.R. §1001.952(h).
- 107. On November 7, 2008, while at a lunch at Eddie Martini's restaurant in Wauwatosa, Wisconsin, Relator personally observed Maupin interacting with Matthew Fermanich, a Forest Laboratories drug representative, and Relator watched Maupin provide Fermanich with a copy of a Drug Utilization Report. Drug Utilization Reports show the number of patients who are prescribed certain drugs, and list the doctors who prescribed that drug. Information on doctors who are not recommending certain prescriptions is very valuable information for drug representatives to have, because they then know which doctors to contact to attempt to steer them towards their product. In a May 11, 2009 e-mail, Maupin told Relator that PharMerica does not allow Drug Utilization Reports to be provided to drug representatives.

Relator personally observed Maupin provide Fermanich the Drug Utilization Report on November 7, 2008.

- manufacturers such as Pfizer and Forest Laboratories are not arms-length transactions and have created illegal kickbacks in violation of 42 U.S.C. § 1320a-7b(b). On information and belief, PharMerica is not disclosing the details of their arrangements to Part D sponsors, doctors, patients or the federal government, who is the ultimate payor through Medicare/Medicaid programs and is adversely affected by these secret arrangements. The purpose of the Anti-Kickback statute is to protect patients and federal health care programs from fraud and abuse by curtailing the corrupting influence of money on health care decisions. By steering physicians towards products of certain drug manufacturers for purely financial gain, PharMerica unjustly limits the health care decisions that prescribing physicians need to make for the benefit of their patients and violates patient confidentiality requirements under the government payment programs..
- 109. The United States of America has been damaged by all of the failures to properly disclose rebates and illegal steering in an as of yet undetermined amount. With respect to the said failures to disclose confidentiality breaches and illegal activites, PharMerica knowingly made false claims to officials of the United States for the purpose of obtaining compensation.
- 110. On information and belief, PharMerica's other facilities also follow the same practices of failing to disclose rebates and illegal steering. On information and belief, PharMerica's corporate-level management is aware of the non-compliant practices and has not taken action to accomplish compliance which would substantially reduce corporate profits.

XI. Count VII. Federal False Claims Act Claim pursuant to 31 U.S.C. § 3729 et seq.:

Violations of the Anti-Kickback Statute By Providing Unsupervised and Uncontrolled

Access to Narcotic Boxes in Exchange for Referral of Patients and Maintenance of Contracts

- 111. Relator reasserts and incorporates by reference all paragraphs set forth above as if restated herein.
- 112. PharMerica provides SNFs with two types of narcotic boxes which contain Schedule II controlled narcotic substances and Schedule III-V controlled narcotic substances, respectively.
- 113. PharMerica does not regularly charge the SNFs for use or delivery of the narcotic boxes and instead creates an impermissible kickback relationship with the SNFs based on their handling of the narcotic boxes.
- 114. To legally use the narcotic boxes, the SNFs are required to complete a narcotic box usage form to PharMerica indicating the date, patient, type of narcotic given, and number of dosages given. PharMerica is required to utilize the use form to complete billing to the United States Government. PharMerica routinely violates these requirements.
- allows SNFs to distribute controlled narcotic substances without billing for the use of the controlled substances. This practice serves as a benefit to the SNFs as the SNF employees are given unfettered access to controlled narcotic substances which PharMerica will simply refill at any time. Upon information and belief, PharMerica provides this uncontrolled access to narcotics as an inducement for SNFs to maintain contracts with PharMerica to have their Medicare patients' prescriptions filled by PharMerica, thus creating a financial benefit to PharMerica and creating an illegal kickback relationship.
- 116. The following are representative examples, of which Relator has personal knowledge, of instances where SNFs completed a narcotic box usage form for scheduled controlled narcotics purportedly distributed to the named patient which were not billed by

PharMerica. In all instances, despite the non-billing of the scheduled controlled narcotics, the narcotic boxes were refilled by PharMerica and delivered to the SNF:

- a. Patient G.H. at the Lasata facility was purportedly given four doses of
 Methadone 5mg, a Schedule II narcotic controlled substance on October
 3, 2008. A narcotic box usage form was completed and submitted to
 PharMerica by the Lasata facility, yet PharMerica intentionally did not
 bill for the usage of the substance;
- b. Patient J.L. at the Watertown facility was purportedly given one dose of Oxycodone 5mg, a Schedule II narcotic controlled substance, on October 2, 2008. A narcotic box usage form was completed and submitted to PharMerica by the Watertown facility, yet PharMerica intentionally did not bill for the usage of the substance;
- c. Patient J.H. at the Village Gardens facility was purportedly given four doses of Methadone 5mg, a Schedule II narcotic controlled substance, on May 29, 2008. A narcotic box usage form was completed and submitted to PharMerica by the Village Gardens facility, yet PharMerica intentionally did not bill for the usage of the substance;
- 117. On information and belief, PharMerica's other facilities also follow the same practices of providing free narcotic controlled substances to SNFs in exchange for the SNFs maintaining contracts with PharMerica to have their patients purchase their drugs through PharMerica. On information and belief, PharMerica's corporate-level management is aware of the non-compliant practices and has not taken action to accomplish compliance which would substantially reduce corporate profits.

XII. Count VIII. Federal False Claims Act Claim pursuant to 31 U.S.C. § 3729 et seq.: Violations of the Anti-Kickback Statute By Accepting Meals in Exchange for Steering Patients to Pharmaceutical Products

- 118. Relator reasserts and incorporates by reference all paragraphs set forth above as if restated herein.
- 119. Relator has direct and personal knowledge of drug company representatives providing meals to PharMerica's pharmacists and members of PharMerica management. Maupin required at least one PharMerica pharmacist to attend the dinners in order to maintain the relationship with the drug company.
- 120. As representative examples of said practice, a Forest Laboratories drug representative named Matthew Fermanich sponsored dinners approximately every other month during Relator's employment. PharMerica's pharmacists and management members from the Pewaukee, Wisconsin location were invited to and attended lavish dinners at restaurants such as the Lake Park Bistro, in or around February 2009, and Bacchus, in or around April 2009. An Eli Lilly drug representative named Brant Meyer sponsored a dinner held at Maggiano's restaurant in or around March 2009. A number of PharMerica employees, including Maupin, attended these dinners which were paid for by the respective drug companies.
- 121. Drug company representatives encouraged PharMerica to invite nurses from the SNFs under contract with PharMerica to attend these lavish dinners. PharMerica did invite nurses from the SNFs to attend the dinners in an effort to further steer the SNFs towards certain preferred medications, and also to maintain contractual relationships with the SNFs by rewarding them for their business and inducing them to continue the business.
- 122. Drug company representatives also provided PharMerica with lunches at the PharMerica Pewaukee, Wisconsin facility. Representatives from Eli Lilly, GlaxoSmithKline,

Ortho Biotech, Pfizer and Forest Laboratories would regularly provide full lunches or would leave food at the PharMerica Pewaukee, WI location for PharMerica'

123. On Such lavish meals provided by drug representatives to PharMerica cause or are intended to cause the purchase of drugs manufactured by the representative's company without regard to cost or medical advantage and consequently the government is sustains damages by inflated drug payment claims. On information and belief, such practice is condoned on the corporate level and practiced at PharMerica's facilities throughout the country.

XIII. Count IX Unlawful Retaliation and Conduct under Federal 31 U.S.C. § 3730(h): Unlawful Retaliation Against Relator

- 124. Relator reasserts and incorporates by reference all paragraphs set forth above as if restated herein.
- 125. 31 U.S.C. §3730(h), provides, "(1) Any employee... shall be entitled to all relief necessary to make that employee... whole, if that employee is... discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee... in furtherance of, other efforts to stop one or more violations of this subchapter."
- 126. On July 20, 2009, Relator sent an e-mail to Christopher Flori ("Flori"), Vice-President of Operations, expressing her need for assistance from PharMerica corporate to achieve compliance with federal and state laws and regulations. Relator informed Flori that she was still not getting assistance from anyone in PharMerica's corporate offices or in the Pewaukee facility, and that the lack of assistance was making her job impossible to do and putting her pharmacy license at risk.
- 127. On July 21, 2009, Maupin called Relator into her office with Hollar on speaker phone. Hollar stated that PharMerica had accepted her resignation and she would not need to

repay her \$10,000 signing bonus. Relator informed Hollar that she did not ask to resign; rather she had asked for help to correct compliance issues and cease the illegal conduct related to dispensing and billing for drugs. Hollar stated that this was Relator's last day. He directed Relator to leave the premises immediately, and stated that she was no longer allowed on the premises. Maupin took Relator's keys to the building, her company laptop, and other company property in her possession. Maupin provided a severance agreement for Relator to sign which characterized the employment separation as a voluntary resignation and included a provision to release all of her potential claims and which would prevent her from recovering sums in a *qui tam* action. The consideration offered was forgiveness of repayment of Relator's \$10,000 signing bonus.

- 128. On July 22, 2009, Relator learned that the DEA was at PharMerica's facility conducting a raid. Relator went to the location and a DEA representative informed PharMerica management that Relator needed to be there because her name was on the pharmacy license. Relator helped the DEA gather the information they demanded. Maupin, Papenthein, and numerous other employees saw Relator interacting with the DEA and assisting them by making sure they received all of the information they requested. At one point, Relator reminded the DEA they had forgotten documents in her office that they had asked to see and Maupin overheard Relator volunteer that information to the DEA.
- 129. Later the same day Relator left a voice mail message for Hollar and informed him that she would not agree to resign or sign the resignation agreement and that he should call her back so she could return to work.
- 130. On July 23, 2009 Hollar called Relator and informed her that all of the previous communications were immaterial because PharMerica had decided to eliminate the POM position at all of their locations and therefore Relator was terminated effective the following day on July

- 24, 2009. According to Hollar, this decision had been made a day earlier, on July 22, 2009 which was the same day of the DEA raid and Relator's public cooperation with DEA agents.
- 131. Several months before her termination, Relator began identifying and attempting to correct compliance and false claims issues at PharMerica.
- 132. As set forth above, relator called to the attention of PharMerica corporate compliance and her own management violations of law governing false claims. On May 4, 2009, Relator informed the DEA that she believed PharMerica was in violation of numerous regulations as described *supra*. She provided assistance and testimony in support of DEA enforcement activities, including at a July 10, 2009 meeting with three assistant U. S. Attorneys and an attorney from the U.S. Department of Justice, and two DEA agents.
- 133. Relator's investigations into: (1) violations of dispensing Schedule II narcotics in non-emergency situations; (2) violations of dispensing emergency narcotics without receiving the required signed prescription within 7 days; (3) violations of illegally dispensing Schedule III-V controlled substances; (4) violations of not crediting Medicare/Medicaid for returned medications and then double billing for the same medications; (5) violations of billing for one medication and providing a patient another medication and; (6) potential violations of the Anti-Kickback Statute, were all lawful acts in furtherance of this action and Relator called them to the attention PharMerica corporate and or her management. In addition, Relator provided lawful assistance to the DEA up to and including in their raid of PharMerica, Pewaukee, WI on July 23, 2009. Because of these lawful acts Relator was terminated in violation of 31 U.S.C. § 3730(h).
- 134. PharMerica was aware of Relator's investigations because, *inter alia*: (a) on numerous occasions, Relator informed her supervisor, Maupin, that the company was not compliant with regulations, and that they needed to take steps to change their behaviors to become compliant with regulations; (b) Relator questioned numerous coworkers about noncompliance; (c)

Relator accessed and printed numerous documents showing noncompliance and would leave the building with them, and; (d) the DEA raided the PharMerica, Pewaukee Wisconsin facility on July 22, 2009, and during the DEA raid Relator was observed by numerous employees, including Maupin and Papenthein, assisting the DEA in their investigation; and e) Relator raised such issues to PharMerica corporate.

- Relator's discharge, PharMerica continued to recruit applicants for POM positions. Recruiting for the POM position was posted on June 24, 2009 at the Nashville, Tennessee location. A POM recruitment notice was also posted on July 10, 2009 at the Beltsville, Maryland location. On July 24, 2009, Relator made phone calls to both locations and confirmed that the managers at each location were still accepting applications for the POM position.
- 136. As of July 31, 2009, PharMerica was recruiting applicants for Relator's Pewaukee POM position after PharMerica terminated Relator. The POM position with a description that matched Relator's job description was posted on various websites.
- 137. PharMerica discharged Relator because of her lawful conduct in furtherance of her efforts to stop PharMerica from violating its requirements for submission of claims to the government. Relator has been damaged by PharMerica's conduct to discharge her employment in an amount as of yet undetermined, but specifically including loss of income and benefits and damage to her career.

PRAYER FOR RELIEF

WHEREFORE, Relator is entitled to damages and the United States is entitled to damages from PharMerica Corporation in accordance with the provisions of 31 U.S.C. §§ 3729-3733, and Plaintiff/Relator requests that judgment be entered against Defendant, and ordering that:

- a. Defendant cease and desist from violating the False Claims Act, 31 U.S.C. § 3729 et seq.;
- b. Defendant pays an amount equal to three times the amount of damages the United States has sustained because of Defendant's actions, plus a civil penalty against Defendant of not less than \$5,000 and not more than \$11,000 for each violation of 31 U.S.C. § 3729;
- c. Plaintiff/Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d);
- d. Grant Plaintiff/Relator such relief as is appropriate under the provisions of 31 U.S.C. § 3730(h) of the False Claims Act;
- e. An injunction be issued to permanently restrain and enjoin Defendant, its agents, employees, and administrators from harassing, retaliating or otherwise discriminating against Plaintiff/Relator or any other person who objects to, protests or discloses fraud or engages in protected activities within the meaning of the Section 3730 of the FCA;
- f. Defendant make Plaintiff/Relator whole for the damages and financial losses suffered as a result of her unlawful discharge in violation of 31 U.S.C. § 3730(h), including two times the amount of backpay, interest on the back pay, and compensation for special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees;
- g. Defendant restore the status quo ante by reinstating Plaintiff/Relator to the position of Pharmacy Operations Manager for PharMerica Pewaukee, Wisconsin;
- h. Plaintiff/Relator be awarded all costs of this action, including attorneys' fees, expenses, and costs pursuant to 31 U.S.C. § 3730(d) and;

i. The United States and Plaintiff/Relator be granted all such other relief as the Court deems just and proper.

PLEASE TAKE NOTICE THAT THE PLAINTIFF DEMANDS THE ABOVE ENTITLED ACTION TO BE TRIED TO A 12 PERSON JURY.

Respectfully submitted and dated this of January 2010.

Cross Law Firm, S.C.

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